Voting Questions
for the
Circulatory System Devices Advisory Panel

June 13, 2012

P110021

Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm and accessories (RetroFlex 3™ Delivery System, models 9120FS23 and 9120FS26; RetroFlex™ Balloon Catheter, models 9120BC20 and 9120BC23; Ascendra™ Balloon Catheter, models 9100BCL23 and 9100BCL26; Ascendra™ Balloon Aortic Valvuloplasty Catheter, model 9100BAVC; Ascendra™ Introducer Sheath Set, model 9100IS;and Crimper, models 9100CR23 and 9100CR26)

The sponsor has proposed the following Indications for Use:

TRANSFEMORAL PROCEDURE

The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for patients with severe symptomatic native aortic valve stenosis who have been examined by a heart team including a cardiac surgeon and found to be:

- inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis, or

- operative candidates for aortic valve replacement but who are at a greater than or equal to 15% (high) risk of mortality for surgical aortic valve replacement.

The RetroFlex Balloon Catheter is indicated for valvuloplasty of a stenotic cardiac valve prior to implantation of the Edwards SAPIEN transcatheter heart valve.

The RetroFlex 3 Delivery System is indicated for the transfemoral delivery of the Edwards SAPIEN Transcatheter Heart Valve.

The Crimper is indicated for use in preparing the Edwards SAPIEN Transcatheter Heart Valve for implantation.

TRANSAPICAL PROCEDURE

The Edwards SAPIEN Transcatheter Heart Valve, Model 9000TFX, sizes 23 mm and 26 mm, is indicated for transapical delivery in patients with severe symptomatic native aortic valve stenosis who have been examined by a heart team including a cardiac surgeon and found to be operative candidates for aortic valve replacement but who are at a greater than or equal to 15% (high) risk of mortality for surgical aortic valve replacement.

The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for valvuloplasty of a stenotic native aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve.

Voting Questions

The Ascendra Balloon Catheter is indicated for the transapical delivery of the Edwards SAPIEN Transcatheter Heart Valve.

The Ascendra Introducer Sheath Set is indicated for the introduction and removal of interventional devices used with the Edwards SAPIEN Transcatheter Heart Valve.
The Crimper is indicated for use in preparing the Edwards SAPIEN Transcatheter Heart Valve for implantation.

The following questions relate to the approvability of the Edwards SAPIEN™ Transcatheter Heart Valve. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented today.

VOTING QUESTION 1: Is there reasonable assurance that the Edwards SAPIEN™ Transcatheter Heart Valve is safe for use in patients who meet the criteria specified in the proposed indication?

VOTING QUESTION 2: Is there reasonable assurance that the Edwards SAPIEN™ Transcatheter Heart Valve is effective for use in patients who meet the criteria specified in the proposed indication?

VOTING QUESTION 3: Do the benefits of the Edwards SAPIEN™ Transcatheter Heart Valve for use in patients who meet the criteria specified in the proposed indication outweigh the risks for use in patients who meet the criteria specified in the proposed indication?